REMARKS

This is a response to the Office Action dated May 16, 2007, in which Claims 1 and 3-8 were rejected. Claims 1 and 3-8 are pending in the application, and are presented for reconsideration and allowance.

Sufficiency of Declaration under 37 CFR 1.131

The Examiner in paragraph 1 of the Office Action, comments on the sufficiency of the Declaration under 37 CFR 1.131. The Examiner states that the phrase "as shown in Berkeley" has not been adequately shown to refer to the publication of Biomedical Microdevices. The Examiner states that the applicant has not provided any factual evidence that the article was published prior to the laboratory notebook page or provide evidence that notebook page is in fact referencing the published article.

The Declaration states that the reference is to the Biomedical Microdevices article. It is respectfully urged that the difference in publishing date and the notebook reference has been explained. The Declaration explicitly clarifies that the inventors understood that the phrase "as shown in Berkeley" refers to the biomedical devices article. The Declaration in combination with the notebook page and the Biomedical Microdevices article are sufficient to show possession of the invention.

The Examiner further states that some language of the claims is not specifically set forth in the notebook page. However, an exhibit need not support all claimed limitations provided that the missing material is supported by the Declaration itself. The Declaration states the claimed invention was conceived in the US prior to the effective date of Chan-1 and Hannah. The Declaration in combination with the notebook page is sufficient to show possession of the invention prior to the filing dates of Chan-1 (US Publication No. 2003/0059822) and Hannah (US 6,767,731). Therefore, it is respectfully requested that the declaration be reconsidered and that the rejections utilizing Chan-1 (US Publication No 2003/0059822) and Hannah (US 6,767, 731) be reconsidered and withdrawn.

Claim Rejection - 35 USC 102

Claims 1 and 3-6 stand rejected under 35 USC 102 as being anticipated by US Patent No. 6,054,327 (Bensimon). The Examiner states that several aspects of the instant claim 1 are broadly interpreted including the phrase "from a reservoir to a microfluidic device" which is interpreted as any movement of the DNA complex in a device to contain small amounts of liquids. Flow through a narrow channel is interpreted is any motion through a small passageway. The Examiner states that Bensimon teaches that probes for hybridizing DNA can be oligonucleotides. Bensimon is also stated to teach a method of aligning DNA placed in a channel between cover slips by evaporation flow parallel to a moving meniscus in the channel. The Examiner also states that Bensimon teaches two probes can be used to analyze DNA and cites the use of multiple probes for the analysis of a DNA molecule. The Examiner states that Bensimon also teaches the analysis of the entire length of a nucleic acid molecule. This rejection is respectfully traversed.

It is respectfully urged that Bensimon does not disclose the step b) hybridizing at least two distinct DNA sequence recognition units to a DNA molecule in a random coil state and then recognizing the units. The Examiner has cited column 13 line 12-24 of Bensimon as teaching this limitation. However, this section of the patent does not set forth a location of two distinct DNA sequence recognition unit's on a target DNA molecule in a random coil state to form a hybridized DNA complex in a random coil state. Further, there is no teaching of a narrow channel that causes an acceleration of fluid flow. The Examiner has referred to Figure 6 as showing a narrow channel. However there is no teaching of acceleration of flow in the channel. As these teachings are not present it is respectfully urged that Bensimon is not anticipating of the invention and it is respectfully requested that the rejection being reconsidered and withdrawn.

Claim Rejection - 35 USC 102

Claims 1 and 3-6 stand rejected 35 USC 102 as anticipated by US Patent Publication in 2003/0059822 (Chan et al. referred to as Chan-1). Chan-1 is stated to disclose a method of analyzing a polymer comprising labeling the polymer with first and second unit specific markings, the first unit specific marker having first

label and the second unit specific marker including a second label distinct from the first label. A labeled polymer is exposed to a detection station to produce distinct detection signals from the first and second labels. Chan-1 is stated to teach that the labels may be the same or different. Chan-1 is also stated to teach the technique of stretching DNA by driving through Micro Channel and teaches detecting optically distinguishable DNA sequence recognition units along a linear hybridized DNA complex. This rejection is respectfully traversed.

Chan-1 is drawn to a method of analyzing polymer by providing the markers on a polymer molecule. This is in contrast to the instant invention where a single molecule identification is carried out by attaching optically distinguishable material to a DNA sequence recognition unit, wherein said DNA sequence recognition unit identifies a specific sequence of DNA in said DNA target molecule. In contrast the instant invention is a method for identifying a target DNA molecule in a random coil state. There is no teaching to utilize the method of Chan-1 to identify DNA molecules. Therefore, Chan-1 is not anticipating of the instant invention and reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejection - 35 USC 102

Claims 1 and 3-8 stand rejected under 35 USC 102 as being anticipated by Hannah et al. US Patent No. 6,767, 731. The Examiner states that Hannah teaches sequencing a target nuclei acid comprising hybridization of the target DNA with probes which can be oligonucleotides and oligonucleotide analogues which are detectably labeled. The Examiner also states that Hannah teaches using a microfluidic device to pass the hybridized nucleic acid through micro channel to expand into a linear configuration. The Examiner states that Hannah also teaches that the probes used for the method can be DNA and that the labels can be fluorescent. With regard to Claim 1 part (d), Hannah is stated to teach analyzing the linear order of probes on target nucleic acid where each probe has a distinct spectral signature. This rejection is respectfully traversed.

The present invention relates to a method for single molecule identification of a target DNA molecule in a random coil state by attaching an optically distinguishable material to a DNA sequence recognition unit, which is specific to a particular sequence of DNA, hybridizing at least two distinct

optically distinguished DNA sequence recognition unit to a target DNA molecule in a random coil state, passing the target DNA molecule, now hybridized with at least two distinct optically distinguished DNA sequence recognition unit, in a fluid carrier from a reservoir in a microfluidic device through a narrow channel to cause an acceleration of fluid flow through said channel, thereby causing the hybridized DNA complex to extend into a substantially linear configuration, detecting the optically distinguishable material in a sequential manner, determining, from this sequence of optically distinguished material, the sequential order of the specific DNA sequences of the target molecule to identify the target DNA molecule from its DNA sequence.

A claim is anticipated only if each and every element, as set forth in the claim, is found either expressly or inherently described in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. Hannah fails to teach attaching an optically distinguishable material to a DNA sequence recognition unit and hybridizing the DNA sequence recognition unit to a target DNA molecule in a random coil state as claimed by the instant invention. The probes disclosed in Hannah are detectable only upon being exposed to an excitation source. In particular an electron beam is used to excite the probes. By contrast, the instant invention claims optically distinguishable material that are colored microparticles. The colored microparticles of the instant invention are optically distinguishable without being excited from an electron beam as taught by Hannah. Therefore, Hannah fails to teach all of the claimed limitations of the instant invention.

The Examiner argues that the microparticles of Hannah which are colored when excited reads on the claim. However, the claims are limited such that the optically distinguished material is attached to the DNA as colored microparticles. This does not read on the disclosure of Hannah, therefore Hannah is not anticipating and it is respectfully requested that this rejection be reconsidered and withdrawn.

Claim Rejections - 35 USC 103

Claims 7 and 8 stand rejected under 35 USC 103(a) as being unpatentable over US Patent Publication No.2003/0059822 (Chan et al referred to as Chan-1) in view of PCT/US00/ 22253 (International Publication Number WO 01/13088 A1) (Chan, referred to as Chan-2). This rejection is respectfully traversed.

The Examiner states that Chan-1 teaches all elements of these claims except for the width or depth of the channel. The Examiner states that Chan-2 teaches the channel with 1 μm depth, 1 mm length, and a shear rate of 0.25/s gives a force of approximately 0 .25 pN, which the inventors have verified experimentally as adequate to stretch DNA. The Examiner states it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Chan-1 with the device of Chan-2 because Chan-2 specifically teaches a device for performing the method of Chan-1. This rejection is respectfully traversed.

With respect to Chan-1, it was argued above that Chan-1 is drawn to a method of analyzing polymer by providing the markers on a polymer molecule. This is in contrast to the instant invention where a single molecule identification is carried out by attaching optically distinguishable material to a DNA sequence recognition, wherein said DNA sequence recognition unit identifies a specific sequence of DNA in said DNA target molecule. Further, the instant invention is a method for identifying a target DNA molecule in a random coil state. There is no teaching to utilize the method of Chan-1 to identify DNA molecules. With respect to Chan-2, there is no teaching to label DNA molecules. Therefore there is no suggestion or disclosure in any combination of Chan-1 or Chan-2 that would lead one to the instant invention. Therefore, it is respectfully requested that this rejection be reconsidered and withdrawn.

Claim Rejections - 35 USC 103

Claims 1, 3 and 4 it stand rejected under 35 USC 103 as being unpatentable over Chan et al. PCT/US 00/22253 (W0 01/13088), hereinafter Chan-2, in view of Bensimon et al. (US Patent 6,054,327). The Examiner states that Chan-2 provides a method for sequence analysis of a single nucleic acid molecule by visual examination of the nucleic acid molecule stretched into a linear confirmation. The Examiner states that Chan-2 does not specifically teach

the labeling of oligonucleotide probes with microparticles. Bensimon is stated to teach methods for analysis of linearized target nucleic acid molecules using oligonucleotide probes that can be labeled with fluorescent labels. The Examiner states it would have been *prima facie* obvious at the time of the invention to have used the oligonucleotide labeling techniques of Bensimon to analyze randomized oligonucleotide probes hybridized to target DNA by the method of Chan-2. This rejection is respectfully traversed.

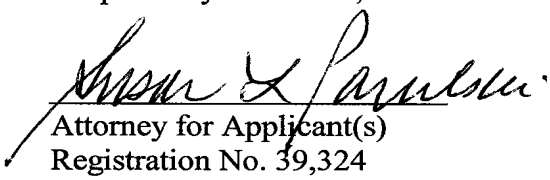
As stated by the Examiner, Chan-2 does not specifically teach the labeling of oligonucleotide probes with microparticles. Bensimon, as urged above, does not disclose the formation of a molecule that has been hybridized to at least two distinct DNA sequence recognition units when the DNA molecule is in a random coil state. There is no disclosure suggestion in Chan-2 to overcome the lack of disclosure in Bensimon and therefore is it is respectfully urged that there is no disclosure or suggestion of the combination. Therefore, it is respectfully requested that this rejection be reconsidered and withdrawn.

Summary

Should the Examiner consider that additional amendments are necessary to place the application in condition for allowance, the favor is requested of a telephone call to the undersigned counsel for the purpose of discussing such amendments.

For the reasons set forth above, it is believed that this application is in condition for allowance. Accordingly, it is requested that the rejections under 35 USC 102 and 35 USC 103 be reconsidered and withdrawn, and favorable action is respectfully solicited.

Respectfully submitted,



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